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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAOUD, CHRISTINE J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/528,225

Applicant(s)

WANG ET AL.

Examiner

Christine J. Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 9-15 is/are allowed.
- 6) ☐ Claim(s) 1-3 and 5-8 is/are rejected.
- 7) ☐ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the fields of search are co-extensive. This is not found persuasive because burden of search can be established by a separate status in the art, as evidenced by classification. In the instant application, Groups I and III may be classified in class 530, subclass 350, where the method is classified in 514/2. With regard to Groups I and III, the search of the two groups is not co-extensive because a search of a chimeric fusion protein comprising insulin B chain and GAD provides no information on a mutant GAD protein, and vice versa. Likewise, claims to a chimeric protein comprising insulin B chain and GAD would not be obvious over a mutant GAD protein and vice versa. Therefore, the inventions are distinct for the reasons provided in the previous Office action, and there is an established search burden for the reasons provided above.

The requirement is still deemed proper and is therefore made FINAL.

It is noted that Applicant failed to respond to the Species Election requirement (see page 3 of paper #9). A phone call was placed to Tamera Pertmer on October 29, 2002 and the species corresponding to claim 9 was elected for the purposes of examination.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

It would appear that for the instant application to obtain benefit of the earlier filed provisional application, 60/068,648, there must be a claim of benefit to the intervening PCT application, PCT/US98/27408. It also would appear that this information should be included in the first line of the specification. If Applicant believes that the Examiner is in error, it is suggested that the MPEP citations be cited as to why this information does not need to be included in the first line of the specification. Applicant's assistance in the regard is appreciated.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate

paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. It is noted that an IDS has not been received into the instant application at the time of the instant Office action.

Drawings

The drawings are objected to because they refer to the subparts of the figure using lower case letters. 37 CFR § 1.84 (U)(1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. The drawings which are labeled "Figure 1a, 1b, and 1c" in the instant specification should be renumbered as Figures 1A, 1B and 1C. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 CFR § 1.84 (U)(1), the Brief Description of the Drawings and the rest of the specification must be corrected accordingly.

Specification

The use of the trademark CYTOXAN has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 1-15 are objected to because of the following informalities: the claims use a number of abbreviations, such as GAD, IDDM and NOD/SCID, for example. A reading of the specification provides explanation of what these abbreviations mean. However, even though the claims are read in light of the specification, limitations from the specification are not read into the claims. It would be helpful and improve clarity if the full terms were used at the first occurrence in the claims where the abbreviations are found. For example, "insulin-dependent diabetes mellitus (IDDM)" would occur the first time "IDDM" is recited. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for chimeric fusion protein constructs in the form of the insulin B-chain fused to the insulin C-chain fused to at least 2 GAD65 peptides, does not reasonably provide enablement for the generic construct of an insulin B-chain fused to at least one GAD 65 peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification teaches a chimeric fusion protein of the general formula insulin B-chain fused to insulin C-chain fused to GAD65 peptide fused to GAD65 peptide. This general formula does not differ except for the possible addition of extra GAD65 peptides and the possible addition of GGG linkers. The prior art at the time of the instant invention was aware that the administration of insulin B-chain and GAD65 peptides would delay the onset of diabetes (see Ramiya et al. J. Autoimmunity. 10: 287-292, 1997). Fusion proteins of GAD65 peptides was also known in the art at the time of the instant invention (Falorni Diabetologia. 39: 1091-1098, 1996). Therefore, there is suggestion to fuse the B-chain of insulin to the GAD65 peptide fusions for the purpose of treating diabetes since the administration of the 2 proteins alone is beneficial. There is motivation for co-administration, and the success of the GAD65 fusions also appear to supply motivation for generating the chimeric molecule. However, there is no expectation of success to fuse the B-chain of insulin with GAD65 peptides in order to obtain a protein which would be useful for treating, delaying or diagnosing diabetes. This is because there is no expectation that a proper immune response would be generated due to potential protein folding issues. Therefore, the specifics of the construct, including the order of the proteins in the chimera, as well as the particular components of the chimera (i.e. insulin C-chain) appear to be critical features of the instant invention. Therefore, the claims are only enabled for those chimeric fusion proteins which comprise (1) insulin B-chain, (2) insulin C-chain, (3) at least 2 GAD65 peptides.

Applicant should note that argument to this rejection may serve as a basis for making an art rejection over the references cited above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 contains the trademark/trade name CYTOXAN. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a drug-induced diabetes model and, accordingly, the identification/description is indefinite.

Allowable Subject Matter

Claims 9-15 are allowed.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 703-305-7519. The examiner can normally be reached on Monday through Thursday, 8:00AM-2:00PM; voice mail service is available.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud